

Demonstration of Capability (DOC and PT)

ID 14482

Current Step is Close DOC Certification

Date Expires is 4/17/2019 12:00:00 AM

Initiated by Breslin Colin

Next Step by Breslin Colin on 5/29/2018 12:42:46 PM

Next Step by Breslin Colin on 5/29/2018 12:42:53 PM

Submit for Peer Review by Breslin Colin on 5/29/2018 12:44:41 PM

Submit PT for QAC Transmittal by Awanya Francis on 5/30/2018 9:55:31 AM

PT Study Results Released by Ockrassa Davis Angela on 6/29/2018 12:46:02 PM

PT Results Accepted; Proceed to Certification Date Assignment by Ockrassa Davis Angela on 6/29/2018 12:46:31 PM

Submit PT for DD Approval by Ockrassa Davis Angela on 6/29/2018 12:48:14 PM

Approve PT by Schupp George on 7/2/2018 8:59:01 AM

Launched Workflow Record Disposition (ID: [14996](#)) on 7/2/2018 8:59:01 AM

Record Disposition Launched; Close DOC by Workflow Action Executor on 7/2/2018 8:59:02 AM

Close DOC Certification

DOC - DOC Certification Date (begin date)

This date should match the date of analysis or workflow submittal to QAC and it's valid for 1 year plus a month.

5/17/2018

DOC - DOC Certification Expiration Date (end date)

This date is the expiration date of the DOC certification, and it is set 1 year and 1 month from the DOC Certification Date (begin date).

6/17/2019

DOC - Workflow Expiration Date

This date should be set to 2 month before the certificate date expires. The cert date expires 1 year and 1 month after the set date.

4/17/2019

DOC - Short Title

Select the appropriate analysis (and matrix) from the list below. For field edits, including additions, contact a system admin.

AIG048A Ignitability by Setaflash

DOC - Certification

PT DOC

DOC - Certification Type

Certification Type	If Other certification, please specify	Instrument Status	If new, list instrument name and serial number.	Comment(s)

DOC - Certification Information

The following date (directly below) indicates when the analyst to which this DOC belongs to is granted authority to operate the listed equipment based upon final approval.

Date of Analysis (study) or Entry (historical)	Dates of Historical Analyses (if applicable)	Work Order Number(s)	Instrument ID

DOC - Analysis Information

Analytical SOP and Revision Number	Analysis Name (abbreviated name)	Matrix	If Other matrix, please specify

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DOC - Additional Preparation Covered by this DOC (if applicable)

DOC - Case Narrative and/or Training Checklist Attachment

DOC - DOC Summary Spreadsheet

Spreadsheet file extension should be .xlsm (if it is not, please convert it by selecting 'save as' and the desired file type)

All sample preparation, calibration, and analytical steps were done by the analyst to which this ADOC applies. (Analyst Review)

Initial ADOC only

All of the analytical steps and at least 1/2 of the sample prep & cal steps were done by the analyst to which this ADOC applies. (Analyst Review)

Continuing ADOC only

The supportive documentation for the DOC Summary Spreadsheet results has been reviewed and meets policy requirements. (Analyst Review)

All data submitted for historical data DOC were analyzed within 10 months to date of DOC submittal and at least 1/2 within 6 months. (Analyst Review)

Exception: The MDL DOC historical data meets the set 40 CFR part 136 frequency requirements.

If this is an initial ADOC (1st time performing the technology), was a training checklist completed? (Analyst Review)

Are there outstanding items from the initial ADOC checklist that need to be addressed? (Analyst Review)

DOC - Analyst DOC Comment

Comment Date	Analyst DOC Comment

DOC - Designated Peer Reviewer

1. Were the data collected for MDLb and MDLs spread over at least 3 batches on 3 separate days?

Analysis and Preparation if applicable

2a. Were the data collected within the last 24 months (analysis date), and does it include the most recent data?

2b. If data with gross failures were present and outlier(s) were removed, is the rationale for their removal documented in this workflow instance?

3. Were the data for MDLb and MDLs reviewed and evaluated to determine the final MDL?

4a. If the newly determined MDL was <0.5 or >2 of the existing MDL, was the MDL updated?

4b. If $>3\%$ of the method blank results were $>$ the existing MDL, was the MDL updated?

5. If the MDL was calculated using data from multiple instruments, were at least 2 spikes/2 method blanks analyzed on different dates per instrument?

Applicable to MDL calculation using data from multiple instruments

6a. Were at least 2 spikes/2 method blanks analyzed on the new instrument?

Applicable to a new instrument when MDL has already been established for existing instrument(s)

6b. Were all new method blank results analyzed on the new instrument below the existing MDL?

Applicable to a new instrument when MDL has already been established for existing instrument(s)

6c. After combining new and existing spike results and recalculating the MDL, is the recalculated MDL within 0.5 to 2 times the existing MDL?

Applicable to a new instrument when MDL has already been established for existing instrument(s)

7a. [QAC] Was the response of the native concentration at a signal to noise ratio of approximately 5-20?

Applicable to MDL determination for a specific sample matrix (based on client request)

7b. [QAC] If $S/N \sim 5-20$, was the matrix-specific MDL determined according to 40 CFR part 136 section B but without spiking additional analyte?

Applicable to MDL determination for a specific sample matrix (based on client request)

7c. [QAC] If $S/N < 5$, was the analyte spiked into the sample matrix to obtain a concentration that gave results with $S/N \sim 10-20$?

Applicable to MDL determination for a specific sample matrix (based on client request)

DOC - MDL Summary Spreadsheet

DOC - Analyst MDL Comment

Comment Date	Analyst MDL Comment

Does the peer reviewer concur with the answers provided by the analyst to which this DOC applies regarding the DOC procedure and documentation?

DOC - Approval Comment (peer)

DOC - Return Comment (Peer)

DOC - Comment Date (peer)	DOC - Return Comment (peer)

If there were outstanding items from the initial ADOC checklist, was there a follow-up?

The supportive documentation for the DOC Summary Spreadsheet results has been reviewed and meets policy requirements. (QAC Review)

DOC - Approval Comment (QAC)

DOC - Return Comment (QAC)

DOC - Comment Date (QAC)	DOC - Return Comment (QAC)

If additional SOP preps deemed "similar" are submitted, does the Deputy Director approve their qualification under this DOC?

If there were outstanding items from the initial ADOC checklist, does the Deputy Director approve the additional documentation provided?

If this is the analyst "initial" ADOC, does the Deputy Director approve the attached training checklist documentation provided?

The supportive documentation for the DOC Summary Spreadsheet results has been reviewed and meets policy requirements. (DD Review)

DOC - Approval Comment (DD)

DOC - Return Comment (DD)

DOC - Comment Date (DD)	DOC - Return Comment (DD)

PT - Information per Study

Study Number	Vendor Catalogue #	Analysis Date	Work Order	PT Transmittal Form(s)
SM-117	SPEI-014		1804012	14484 1804012 Ignitability by Setaflash FINAL NSI PT SXSAMP 29 May 18 1239.xlsm View

If a LIMS EDD is attached, does it meet the file format requirements stated in the pertinent work instruction? (Analyst Review)

Yes

PT - Analyst Processing Comment

Date of Analyst Processing Comment	Analyst Processing Comment
5/29/2018	PT for flashpoint.

PT - Designated Peer Reviewer

Awanya Francis(540)

If a LIMS EDD is attached, does it meet the file format requirements stated in the pertinent work instruction? (Peer Review)

Yes

PT - Approval Comment (peer)

I approve.

PT - Return Comment (Peer)

PT - Comment Date (peer)	PT - Return Comment (peer)

PT - QAC Processing Comment/Request

Date of QAC Comment/Request	QAC Processing Comment/Request

PT - Date Submitted for Transmittal 5/30/2018

PT - Date Transmitted to Provider and Uploaded to Qualtrax

PT - Accepted by Study?

Yes 100% Accepted Analytes

PT - Evaluation Note (QAC)

Date of Evaluation Note	Evaluation Note (QAC)
6/29/2018	all good

PT - Latest Provider Eval Rpt (Attachment)

PT - Name of Analyte(s) Not Accepted

Date of Documentation	Name of Analyte(s) Not Accepted

PT - Failed analyte(s) tracked by QAC?

Failed analytes must be documented on the tracking spreadsheet.

PT - Responsible Party

Corrective Action Due Date

PT - Investigation Documentation

Date of Investigation	Investigation Documentation

PT - Investigation Attachment(s)**PT - Investigation Review Comment**

Date of Comment	Investigation Review & Effectiveness Comment

PT - Return for Additional Investigation Info

Date of Request	Additional Investigation Info Request

PT - Study (Re-Do) Information

PT Study (Re-Do) ID and Open/Close Dates	PT Study (Re-Do) Ordered Date

PT - Approval Comment (DD)approved
